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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,781	06/15/2001	Carla H. Kuhner	HER-0050	9997

7590 01/20/2004
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,781

Applicant(s)

KUHNER ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 8-15, 21-29 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-20 and 30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 7/20/01
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/5/02
11/4/02
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Formula I (alkyl-CO-Arg-Trp-NH₂) in the response filed March 20, 2003 is acknowledged. The traversal is on the ground(s) that in order for restriction to be proper, the inventions must be shown to be independent and distinct, and there must be a serious burden on the examiner, such as a showing of a separate classification, separate status in the art, or a different field of search. (MPEP 803). Applicants assert that the claims at issue are directed specifically to methods of preventing, inhibiting, or terminating the growth of at least one microbe by administering an antimicrobial peptide of Formula I or Formula II. As such Applicants assert that the invention as defined by claims 27-29 is incapable of being practiced without an antimicrobial peptide of Formula I or Formula II. Applicants further assert that "Normally ten biomolecules constitutes a reasonable number, only in exceptional cases, such as where a protein amino acid sequence reciting three dimensional folds is claimed will the reasonable number of biomolecules examined in an application be less than 10. (MPEP 803.04)

It is further noted that Applicants indicate that the Examiner has quoted a new Office Policy whereby a single sequence or structure constitutes a reasonable number of inventions for examination. Applicants have mischaracterized the Examiners statement.

This is not found persuasive because the Examiner never cited a new Office Policy for restriction to a single sequence, rather MPEP 803.04 sets forth that molecules with a separate sequence are separate inventions, and that a single sequence is within the metes and bounds of "up to 10" sequences. Given that each of the recited structures are distinct chemical compounds, restriction as set forth by MPEP 803.04 is proper. Furthermore, Applicants appear to be under the misguided impression that their claims don't encompass an unreasonable number of biomolecules for a single search as set forth in MPEP 803.04. Applicants attention is respectfully directed to claim 5 which recites SEQ ID NO: 1-23, is 23 greater than 10? Further consider that every single one of these sequences is then structurally modified in a particular way, the number of structure searches that must be carried out becomes logarithmically multiplied.

Furthermore, concerning Applicants comment that the Examiners reasoning is misplaced in that the claims 27-29 are incapable of being practiced without an antimicrobial peptide of Formula I or Formula II are noted. However, Applicants are respectfully directed to MPEP 806.05(h) which sets forth that a product and process of use can be restricted if "the process for using the product as claimed can be practiced with another materially different product." As the Examiner has already clearly set forth, methods of inhibiting the growth of microbes has been practiced for decades with materially different products than those recited in the instant invention. (Tetracycline, Penicillin). Accordingly, restriction is proper.

Consequently, claims 1-31 are pending in the instant application, of which claims 8-15, 21-29, and 31 are withdrawn from further consideration as being drawn to a non-elected invention.

Claims 1-7, 16-20 and 30 will be examined only to the extent that they encompass the elected structure of alkyl-CO-Arg-Trp-NH₂, all limitations which recite a structure change (e.g., Lys-Trp, Orn-Trp, etc.) are also withdrawn from further consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. Claims 1-7, 16-20 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-7, 16-20, and 30, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-7, 16-20 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gloor et al.

The claims are directed to an antimicrobial peptide represented by Formula I.

Gloor et al (US Patent Number 3,265,682) disclose of compounds of the formula recited in claim 1, which further contain alkyl side chains. (See claims).

3. Claims 1-7, 16-20 and 30 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eisenbach-Schwartz et al.

The claims are directed to an antimicrobial peptide represented by Formula I, wherein the Formula is alkyl-CO-Arg-Trp-NH₂, wherein the alkyl group is C1 to C9 including cycloalkyl groups.

Eisenbach-Schwartz et al (US Patent Number 6,126,939) disclose of anti-inflammatory dipeptides including dipeptides of Arg-Trp-NH₂. (See column 3).

Eisenbach-Schwartz et al further set forth of generating derivatives of the dipeptides comprising alkylation of the dipeptide. (See columns 8-9).

It is noted that Eisenbach-Schwartz et al do not disclose that the peptide displays antimicrobial activity, however this is merely an intended use of the peptide, and consequently carries no patentable weight when compared to the identical structure as disclosed by Eisenbach-Schwartz et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Mark Navarro
Primary Examiner
January 8, 2004